REMARKS/ARGUMENTS

It is respectfully requested that this application be reconsidered in view of the above amendments and the following remarks and that all of the claims remaining in this application be allowed.

Amendments

Claim 1 was amended to recite that the administration of the therapeutic agent which results in at least partial remission of one or more of the symptoms of the autoimmune or alloimmune disease is conducted concurrently with administration of the treated autologous mammalian blood.[1] Claim 1 was further amended to recite that the concurrent administration of the treated autologous mammalian blood maintains remission of one or more the symptoms of the autoimmune or alloimmune disease after the therapeutic treatment is terminated. Support for these amendments is found in Applicants' specification in, for example, the second full paragraph at page 8 as well as in originally presented Claim 10.

In view of the amendments to Claim 1, Claim 10 has been withdrawn without prejudice or disclaimer.

Claim 11 was amended to place this claim into independent form. This claim recites a method that first comprises administration of a therapeutic agent which results in at least partial remission of one or more of the symptoms of the autoimmune or alloimmune disease. Once remission is effected, this claim has been amended to recite termination of the administration of the therapeutic agent and then subsequent administration of a sufficient amount of treated autologous mammalian blood to maintain remission. Support for the recitation of subsequent administration is found in Applicants' specification in, for example, the second full paragraph at page 8.

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[1] The term treated autologous blood as used in this response refers to autologous blood treated in the manner of Claim 1 or Claim 11.

Claims 12-19 are newly entered and correspond to and are supported by previously presented Claims 2-9.

Entry of these amendments is earnestly solicited.

Upon entry of these amendments, Claims 1-9 and 11-19 will be pending in this application.

Drawings

Applicants acknowledge that the drawings submitted on January 31, 2003 have been approved by the Draftsman.

Concerning the specification/title

The Examiner has indicated that the title of the invention is not descriptive. The following title was suggested in the Office Action:

--COMBINATION THERAPY USING MODIFED AUTLOGOUS BLOOD FOR TREATMENT OF RHEUMATOID ARTHRITIS--.

Applicants respectfully decline to amend the title. Specifically, examination of rheumatoid arthritis as a species of an autoimmune or alloimmune disease was in response to an election of species requirement included within the Office Action mailed September 5, 2000 (paper no. 6). In this regard, under examination guidelines set forth in the MPEP §809.02(a), a determination that the generic claim is not allowable must be made prior to limiting the claim to this specific species. Applicants maintain that such a determination has not been made and, accordingly, submits that any such amendment to the title is premature. Accordingly, Applicants request the request for title change be held in abeyance until resolution of the patentability of the generic claims.

Concerning rejection of claims under 35 U.S.C. § 103(a)

A. Claims 1-11 stand rejected as allegedly being unpatentable under 35 U.S.C. §103(a) over Bolton, U.S. Patent No. 5,680,954 ("Bolton II"), and Jacobs, et al., U.S. Patent No. 5,605,690, ("Jacobs"). For the following reasons, this rejection is traversed.

In response, Applicants repeat and maintain the arguments set forth in their Appeal Brief that neither Bolton II nor Jacobs, either alone or in combination, establish a *prima facie* case of obviousness. These arguments are incorporated herein by reference in their entirety and Applicants respectfully request withdrawal of this rejection.

Notwithstanding the above, Applicants submit that this rejection is further in error, particularly as it applies to now presented Claims 11-19. Specifically, these claims are directed to the sequential treatment of an autoimmune or an alloimmune disease wherein initially the claimed method comprises administration of therapeutic treatment to effect at least partial remission of one or more symptoms of the disease. Subsequently, the therapeutic treatment is terminated and then the method comprises administration of treated autologous mammalian blood to maintain the remission.

As to these claims, a *prima facie* case of obviousness is established only after three basic criteria have been met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the combined prior art references must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicants' disclosure. *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

In this regard, the sequential treatment of an autoimmune or an alloimmune disease as embodied in Claim 11 comprises:

administration of therapeutic treatment to effect at least partial remission of one or more symptoms of the disease;

termination of this therapeutic treatment; and

administration of treated autologous mammalian blood to maintain the remission.

Such sequential treatment is neither taught nor suggested by either Bolton II or Jacobs. In fact, Bolton II merely teaches use of a vaccine comprising an aliquout of modified autologous mammalian blood[2] for the treatment of autoimmune diseases such as rheumatoid arthritis. There is no teaching or suggestion in Bolton II for the use of his vaccine to maintain remission of symptoms of rheumatoid arthritis let alone where such remission has been achieved by therapeutic treatment.

Likewise, Jacobs is similarly deficient. As noted in the Appeal Brief, the only specifically disclosed combination therapy illustrated by Jacobs is that of a TNF antagonist (i.e., receptor agonist) with an interleukin-1 or-2 receptor agonist. See, e.g., column 13, line 61, through column 14, line 2; column 17, lines 24-28; and column 18, lines 10-40. There is no disclosure, however, in the Jacobs reference of a combination therapy wherein a first component places the autoimmune or alloimmune disease in remission and the second and subsequently administered component maintains such remission.

The Office Action cites *In re Kerkhoven*, 205 U.S.P.Q. 1069 (CCPA 1980) to allege a *prima facie* case of obviousness based on the allegation that it is obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the same purpose. Applicants submit, however, that the subsequent administration of treated mammalian blood after termination of the therapeutic treatment as now recited in Claims 11-19 does not constitute a combination of two compositions. Moreover, the recited use of treated mammalian blood in Claim 11 after termination of therapeutic treatment is not for the same purpose of Bolton II, which was to relieve the symptoms of an autoimmune disease,

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[2] In this case, the term "modified autologous mammalian blood" is meant to conform to the definition provided by Bolton II.

but, rather, is for the purpose of maintaining remission of the autoimmune disease achieved by the therapeutic treatment.

In view of the above, Applicants submit that Claims 11-19 are further distinguished over Bolton II and Jacobs and the rejection of these claims under 35 U.S.C. §103(a) over Bolton II and Jacobs is in error. Withdrawal of this rejection as applied to these claims is requested.

B. Claims 1-11 stand rejected as allegedly being unpatentable under 35 U.S.C. §103(a) over Bolton, U.S. Patent No. 5,591,457 ("Bolton I") and Jacobs (cited above). For the following reasons, this rejection is traversed.

Initially, Bolton I is the parent of Bolton II wherein Bolton II is a continuation-in-part of Bolton I.[3]

Secondly, Applicants maintain, as does the Office Action, that the relevant sections of Bolton I are found at Col. 7, lines 28-38, where there is a disclosure of use of modified mammalian autologous blood in the treatment of autoimmune diseases such as rheumatoid arthritis. There is no disclosure other than this and, as such, this disclosure does not add anything over Bolton II discussed above. In addition, the Jacobs reference was discussed above. Accordingly, for the reasons set forth at length above, Applicants maintain that this rejection is in error.

Withdrawal of this rejection is requested.

Concerning rejection of claims under double patenting

Claims 1-11 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-12 of Bolton II in view of Jacobs. For the following reasons, this rejection is traversed.

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[3] The use of Bolton I and Bolton II in this case is done on a parent/child basis. That is to say that Bolton I is the parent of Bolton II.

Initially, a double patenting rejection of the obviousness-type is analogous to a failure to meet the non-obviousness requirement of 35 U.S.C. §103 except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite,* 154 U.S.P.Q. 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. §103 obviousness determination. In re Braat, 19 U.S.P.Q.2d 1289 (Fed. Cir. 1991). See, for example, MPEP §804(b)(1).

As to the above, Applicants repeat and maintain their position that the subject matter of now presented Claims 1-19 are non-obvious over Bolton II in view of Jacobs. Accordingly, withdrawal of this rejection is requested.

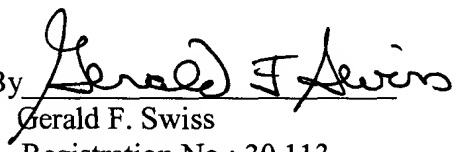
CONCLUSIONS

Applicants have made a sincere effort to overcome the rejections and address all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant(s) petition(s) for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 033136119.

Dated: July 7, 2003

Respectfully submitted,

By 

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